

IN THE SECOND CIRCUIT COURT FOR DAVIDSON COUNTY, TENNESSEE  
 TWENTIETH JUDICIAL DISTRICT AT NASHVILLE

STATE OF TENNESSEE, *ex rel.*  
 ROBERT E COOPER, JR, ATTORNEY  
 GENERAL and REPORTER,

Plaintiff,

v

BAYER CORPORATION, a foreign  
 corporation,

Defendant

No 07C227

JOINT MOTION TO AMEND AGREED FINAL JUDGMENT

The parties move this Honorable Court to approve an amendment to the Agreed Final Judgment entered in the above captioned matter solely as follows

1 On or about January 23 2007 the parties in the above captioned matter entered into and the Court approved an Agreed Final Judgment (attached as Exhibit 1)

2 Following the Agreed Final Judgment certain state Attorneys General contacted Defendant regarding the issues identified in the Warning Letter issued by FDA s Division of Drug Marketing Advertising and Communications ( DDMAC ) dated October 3 2008 (attached as Exhibit 1 to the Order Modifying Agreed Final Judgment and hereafter referred to as Warning Letter )

3 As a result the parties jointly move to modify the Agreed Final Judgment to add the following terms as set forth below which shall be incorporated into the Agreed Final Judgment by this reference as though set forth fully therein

a Section I Definitions is modified to add Paragraphs X and Y as follows

- 1 Paragraph X Modification Signatory Attorneys General shall mean the Attorney General or his or her designee of each of the following states that have agreed to this modification of the Agreed Final Judgment Arizona Arkansas California Connecticut Delaware, Florida Idaho Illinois Iowa Kansas Kentucky Maine Maryland Massachusetts Michigan Mississippi Montana Nevada North Carolina, Ohio Oregon Pennsylvania South Dakota Tennessee Texas Washington and Wisconsin
- 11 Paragraph Y YAZ® shall mean the oral contraceptive product composed of a combination of drospirenone and ethinyl estradiol approved for marketing by FDA pursuant to NDAs 21 676 21 873 and 22 045 under the brand name YAZ®

b Section II Background is modified to add Paragraphs 6 and 7 as follows

- 1 Paragraph 6 Bayer enters into this Modification solely for the purpose of resolving the Modification Signatory Attorneys General's investigation under both the Agreed Final Judgment and their respective states consumer protection statutes into the issues identified in the Warning Letter issued by FDA's Division of Drug Marketing Advertising and Communications (DDMAC) dated October 3 2008 (attached as Exhibit 1 and hereafter referred to as Warning Letter) to avoid unnecessary expense inconvenience and uncertainty without admitting any violation of the Agreed

Final Judgment or state consumer protection statutes and without admitting any wrongdoing and for settlement purposes only

11 Paragraph 7 This Modification is made without adjudication of any issue of fact or law or finding of wrongdoing or liability of any kind. It is the intent of both Bayer and the Modification Attorneys General that this Modification shall not be admissible in any other matter or proceeding and shall not bind Bayer in any respect other than in connection with the enforcement of this Modification. Except in an action by the Modification Attorneys General to enforce this Modification, this Modification shall not be construed or used as a waiver or limitation of any defense otherwise available to Bayer or of Bayer's right to defend itself or make arguments in any other matter related to the issues identified in the Warning Letter.

c In addition to the terms contained in the Agreed Final Judgment, Section XIV YAZ® Advertising is added with the following Paragraphs: Pursuant to Tenn. Code Ann. § 47-18-108(a)(4), Bayer is hereby ordered adjudged and decreed without a cost bond as follows:

1 Bayer shall disseminate corrective advertising that addresses the issues identified in the Warning Letter. The corrective advertising campaign shall consist of a television advertisement and a print advertisement that have been approved by DDMAC and reviewed by the Modification Signatory Attorneys General prior to

submission of this Joint Motion. The television advertisement shall be broadcast on national cable and network television and the print advertisement shall be published in magazines with national distribution. The specific content and timing of this advertising campaign shall be as specified and approved by DDMAC and reviewed by the Modification Signatory Attorneys General prior to the submission of this Joint Motion. Bayer shall spend at least \$20 million on this corrective advertising campaign. Bayer's dissemination of the advertising described in this paragraph shall not be construed as an admission by Bayer that the advertisements identified in the Warning Letter were false, misleading, or deceptive in any manner. Nor shall Bayer's dissemination of the advertising described in this paragraph be considered evidence of any liability, wrongdoing, or fault by Bayer.

- 11 Bayer agrees to submit all new Direct to Consumer ( DTC ) television advertising campaigns for YAZ® to FDA for pre review, wait until Bayer receives a response from FDA prior to running the advertising campaign, and to modify such advertising consistent with any final written comments received from FDA. Non material modifications to existing advertising campaigns are not covered by this paragraph.
- 111 Bayer shall not run print advertising for YAZ suggesting or marketing YAZ®'s effectiveness at treating selected symptoms of

- the FDA approved indication(s) unless the drug's specific FDA approved indication(s) is/are stated as clearly and conspicuously in the same promotional spread as the symptoms referenced
- iv Bayer's obligations with respect to paragraphs ii and iii shall remain in effect for six years following the date this Order Modifying Agreed Final Judgment is entered by the court
- v Bayer shall submit to each Modification Signatory Attorney General on the anniversary of the Effective Date of this Modification a written affirmation setting forth Bayer's compliance with Section XIV
- d In addition to the terms contained in the Agreed Final Judgment Section XV RELEASE RE YAZ® is added and with the following paragraphs
- i Section XV shall pertain to the product YAZ® only and does not alter or modify the release set forth in Section VII of the Agreed Final Judgment
- ii Based upon their investigation into Bayer's promotional and marketing practices regarding YAZ® and whether those practices violate the Agreed Final Judgment, the Modification Signatory Attorneys General have concluded that the Agreed Final Judgment as modified per this Order Modifying Agreed Final Judgment is the appropriate resolution of any alleged violations of the Agreed Final Judgment by Bayer regarding its marketing and promotion of

the product YAZ® as described by the Warning Letter attached as Exhibit 1 and incorporated by this reference as though set forth in full

- iii In Consideration of the terms set forth in Section XIV by execution of this modification of Agreed Final Judgment each Modification Signatory Attorney General, as defined in Section I Paragraph X releases and forever discharges to the fullest extent permitted by law Bayer and all of its past and present officers directors, shareholders employees affiliates, subsidiaries predecessors assigns and successors (hereinafter referred to collectively as the Released Parties ) from contempt proceedings that were or could have been asserted against the Released Parties by the Modification Signatory Attorneys General for the marketing and promotion of YAZ® by engaging in only the specific conduct described in the Warning Letter attached hereto as Exhibit 1 and incorporated by this reference as though set forth in full
- iv The Modification Signatory Attorneys General also release and forever discharge to the fullest extent permitted by law the Released Parties from any other claims or causes of action under the following consumer protection statutes ARIZONA Consumer Fraud Act A R S § 44 1521 et seq ARKANSAS Deceptive Trade Practices Act Ark Code Ann § 4 88 101 et seq CALIFORNIA Bus & Prof Code § 17200 et seq

CONNECTICUT Connecticut Unfair Trade Practices Act Conn  
 Gen Stat § 42-110a et seq DELAWARE Delaware Consumer  
 Fraud Act 6 Del C § 2511 et seq and Deceptive Trade Practices  
 Act 6 Del C §2532 et seq FLORIDA Deceptive and Unfair  
 Trade Practices Act, Fla Stat Ch 501 201 et seq IDAHO  
 Consumer Protection Act Idaho Code § 48-601 et seq ILLINOIS  
 Consumer Fraud and Deceptive Business Practices Act 815  
 ILCS § 505/1 et seq IOWA Iowa Consumer Fraud Act Iowa  
 Code Section 714 16 KANSAS Consumer Protection Act  
 K S A 50-623 et seq KENTUCKY Consumer Protection  
 Statute KRS 367 170 MAINE Unfair Trade Practices Act 5  
 M R S A § 205 A et seq MARYLAND Consumer Protection  
 Act Md Code Ann Com Law § 13-101 et seq  
 MASSACHUSETTS Consumer Protection Act M G L c 93A et  
 seq MICHIGAN Consumer Protection Act Mich Comp Laws  
 § 445 901 et seq MISSISSIPPI Consumer Protection Act Miss  
 Code Ann § 75-24-1 et seq MONTANA Mont Code Ann § 30  
 14-101 et seq NEVADA Deceptive Trade Practices Act Nevada  
 Revised Statutes 598 0903 et seq NORTH CAROLINA Unfair  
 and Deceptive Trade Practices Act N C Gen Stat § 75-1-1 et  
 seq OHIO Consumer Sales Practices Act R C 1345 01 et seq  
 OREGON Unlawful Trade Practices Act ORS 646 605 to  
 646 656 PENNSYLVANIA Unfair Trade Practices and

Consumer Protection Law 73 P S § 201 1 et seq SOUTH  
DAKOTA Deceptive Trade Practices Act, S D Codified Laws  
§ 37 24 et seq , TENNESSEE Tennessee Consumer Protection  
Act, Tenn Code Ann §§ 47 18 101 et seq TEXAS Deceptive  
Trade Practices Consumer Protection Act Tex Bus and Com  
Code § 17 47 et seq WASHINGTON Unfair Business  
Practices/Consumer Protection Act R C W 19 86 et seq  
WISCONSIN Wis Stat § 100 18 et seq (Fraudulent  
Representations) and Wis Stat § 100 182 et seq (Fraudulent Drug  
Advertising) that were or could have been asserted against the  
Released Parties by the Modification Signatory Attorneys General  
for the marketing and promotion of YAZ® by engaging in only the  
specific conduct described in the Warning Letter attached hereto as  
Exhibit 1 and incorporated by this reference as though set forth in  
full This release does not extend to conduct or advertisements by  
the Released Parties that were not specifically described in the  
Warning Letters attached hereto as Exhibit 1 including but not  
limited to conduct that occurred prior to or subsequent to the  
described conduct conduct pertaining to advertisements not  
addressed in the Warning Letter or conduct beyond the scope of  
what is described in the Warning Letter

e Notwithstanding any term of this Modification specifically reserved and



excluded from the Released Claims as to any entity or person including Released Parties are any and all of the following

1 Any criminal liability that any person or entity, including Released Parties has or may have to any or all of the Signatory Attorneys General

11 Any civil or administrative liability that any person or entity including Released Parties has or may have to any or all of the Signatory Attorneys General under any statute regulation or rule not expressly covered by the release in Paragraph 111 above including but not limited to any and all of the following claims

1 State or federal antitrust violations

2 Reporting practices including best price 'average wholesale price or wholesale acquisition cost

3 Medicaid violations including federal Medicaid drug rebate statute violations Medicaid fraud or abuse and/or kickback violations related to any State's Medicaid program

4 State false claims violations and

5 Claims to enforce the terms and conditions of this Modification

111 Any liability under the above cited consumer protection laws of any or all of the Modification Signatory Attorneys General which any person or entity including Released Parties has or may have

to individual consumers or State program payors of said Individual States and which have not been specifically enumerated as included herein

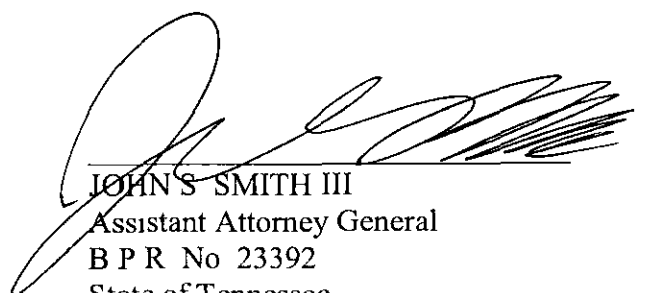
4 The parties assert good cause exists to modify the Agreed Final Judgment to resolve concerns about certain conduct by Defendant

Wherefore the State and the Defendant respectfully request that the Court approve the Agreed Order to Amend

Respectfully submitted

FOR PLAINTIFF STATE OF TENNESSEE

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